

From Human Tissue to Human Bodies

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From *Human Tissue* to *Human Bodies*: Donation, Interventions, & Justified Distinctions?

Abstract

*This article reviews the latest report from the Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research*. It argues that the report represents a notable evolution in the Council's position regarding the appropriate governance of the human body and biomaterials. It then goes on to examine in more depth one of the report's recommendations – that a pilot payment scheme for eggs for research purposes should be trialled. In particular, it looks at whether the distinctions drawn, first, between eggs for research and therapeutic purposes and, secondly, between eggs for research and other biomaterials can be adequately justified.*

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1. Introduction

The latest report from the Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research*,¹ was published in October 2011. The foreword identifies the main task of the report as examining the question “how far can society go in its demands on people to act in what many regard as a good cause – that of providing bodily material to benefit others?” As such, it explores the ethical, legal, and social implications of individuals providing tissue and other biomaterials for both medicine and research. This encompasses a diverse range of biomaterials including not only blood (products), solid organs, tissue, gametes, embryos, and fetal material, but also the whole body after death and the living person as research subject (p.35).¹ The activities and circumstances involving the use of the biomaterials are no less wide-ranging. The result is a comprehensive and informative report.²

There is not space in what follows to outline all of the conclusions and recommendations contained in the report.³ Instead I examine the rationale for the support given to introducing a pilot payment scheme for eggs for research purposes should be trialled. I do this in order to examine whether the distinctions drawn, first, between eggs for research and therapeutic purposes and, secondly, between eggs for research and other biomaterials can be adequately justified. I also focus on these as a way of illuminating some aspects of the wider issue which pervades the report; the question of what constitutes an appropriate intervention in order to promote the donation of biomaterials. Before specifically looking at these, however, a look at the background to the report is warranted to illustrate how the advances in the biomedical arena have led to an evolution in policy-orientated thinking with respect to the governance of human biomaterials.

2. Human tissue & (r)evolutionary principles?

In 1995 the Nuffield Council published *Human Tissue: Ethical and Legal Issues*.⁴ This report dealt with similar issues to the current one, remarking that “[o]ne aspect of the recent and rapid advances in biological and medical research is that human tissue is being used in an increasing variety of new ways” (p. 1).⁴ Among the uses noted were blood transfusion, bone marrow transplantation, organ transplantation and reconstructive surgery, tissue replacement, studies of human tissue, diagnosis using cells, cell lines (basic and applied research), pathological examination, archiving and storage, and non-therapeutic applications such as DNA analysis for forensic purposes (pp. 31-8).⁴ The report provided a comprehensive analysis of many of the pertinent issues, along with a set of ethical, legal, and regulatory recommendations regarding uses of human tissue. Such uses of these materials, taken from both the living and the dead, might now seem commonplace to us. Yet, in the interim, biotechnological and medical developments have continued apace, with the Council noting that it has been a time of “considerable scientific, social, and legal change”.⁵ This prompted them revisit the issues and to launch another consultation in early 2010.⁶ The resultant report represents a notable evolution in the Council’s position regarding the appropriate governance of the human body and biomaterials since its 1995 report.

This evolution is most evident with regards to the issue of payments. The earlier report was strongly against the “procurement of human tissue for acceptable medical and scientific purposes along commercial lines” (p. 52).⁴ Among other things it considered that permitting market transactions for human tissue might undermine consent, subvert altruistic motivations, and have negative implications for the safety of tissues supplied (pp. 50-1).⁴ Conversely, the stance of the current report in relation to payment and altruism is more developed and nuanced. It recognises both that payments can take varied forms (and thus have different social meanings) and that they need not be damaging to an individual’s altruistic motivations. Regarding consent, the report says “we do not accept that the *very existence* of an incentive puts the free and voluntary nature of a person’s consent at risk” (p. 148).¹ On the issue of safety the concern noted in the current report is that the biomaterials procured might be “more likely to be infected, unhealthy, or low-functioning” (p. 142).¹ However, a review commissioned by the Council concluded that there is little empirical evidence in support of this proposition (pp. 165-7),¹ but even if it were the case that “the remedy surely lies in an effective system of monitoring and quality-control” (p. 142).¹

In the next section I explore the Council’s current stance in relation to payments and altruism. However, before I do, it is worth noting that the shift in position is evident not just in the substantive content of the report, but in the language employed. The earlier report spoke of ‘commercial dealings’ and ‘markets’, whereas the current one talks of ‘rewards’, ‘incentives’, and ‘purchase’, none of which have the same connotations. This is more than simply dressing up the same issues in different clothing.

It is a re-framing of the debate and the issues in order to more aptly reflect the diversity of considerations at play regarding human biomaterials in contemporary biomedical science. A broad brush one size fits all approach is not going to capture the relevant factors that ought to be accounted for when thinking about how best to govern donation for medical and research purposes. This is not necessarily a criticism of the older report. The recommendations contained in it reflected the state-of-the-art of the use and uses of human tissue within biotechnological landscape and also the academic and policy debates of the time. However, sixteen years is a long time in medicine and the biosciences and the fast-pace of developments in the area rightly prompted the Council to re-visit the matter.

3. Interventions: Payments & altruism

The rubric, and some might say rhetoric, of altruism holds considerable sway in the ethical and policy debate on human tissue, in particular in relation to organ donation. A nuanced approach to this issue of incentives for human biomaterials has been advocated from within the academy for some time, even amongst those who reject the introduction of outright payments.^{7,8,9,10,11,12} However, it has taken some time for this to start to trickle down to more policy-orientated fora. This latest report from the Nuffield Council is an example of where this is happening. It notes that while altruism “should continue to play a central role in ethical thinking in this field”(p. 156),¹ other approaches are not precluded. They recognise any requirement that a donor’s altruism be ‘pure’ belies the complexity behind decisions to provide organs and tissues for either transplantation or research and that persons may have “mixed motivations” for donating (p. 139).¹ The report is clear that altruism and interventions classed as ‘payment’ need not be “mutually exclusive” (p. 139).¹ While a person may be motivated by a desire to help others when they donate biomaterials, there may also be other reasons and factors at play; for example, worries about loss of income might deter someone from becoming a living kidney donor. In such cases permitting the reimbursement of expenses and lost earnings could be seen as a facilitator of rather than an encumbrance to a person’s altruistic motivations (pp. 139-40).^{1,12} Thus, the report explicitly recognises that there may be times when it is appropriate to allow payments to be permitted for human biomaterials.

We should note, however, that ‘payment’ in the report is an overarching term which includes purchase, reward, and recompense: (1) recompense is defined as *reimbursement* for direct financial losses brought about because of the donation, including “*compensation* for non-financial losses (discomfort, inconvenience, and time)” (p. 70);¹ (2) reward as receiving *material advantage* over and above mere recompense to a person for donating; and (3) purchase as the *direct exchange* of bodily materials for payment (p. 70).¹ Although distinctions are drawn between the three categories of payments, it is not done with the purpose of arguing that only payments which count as recompense ought to be permitted. It does not

seem overly contentious, in the case of the reimbursement example above, to suggest that individuals who donate organs for transplantation or tissues for research ought not to be left financially worse off because they do so. The report, however, goes further than this. It makes a case for offering rewards and recompense in certain well-circumscribed situations; for example, paying funeral costs for those who sign up to the Organs Donor Register and "die in circumstances where they could be organ donors" (p. 175)¹ and recompense beyond actual financial losses incurred for eggs donated for research. The latter of these will be discussed later.

Whether or not it is appropriate to offer payments in particular circumstances is a context-specific question and is part of the wider task of determining which interventions ought to be pursued given the diverse uses and ends of human biological materials. Mindful of this, the report outlines six levels of interventions (their 'intervention ladder') which are seen as moving from altruism-focused to non-altruism-focused:

1. relaying **information** about the need for bodily material for others' treatment or for research (for example information campaigns);
2. according **recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned (for example letters of thanks and certificates);
3. intervening to **remove barriers and disincentives** to donation (for example ensuring full reimbursement of financial losses incurred in donating);
4. offering **token prompts** to donate that may also be understood as a 'thank you' (for example lottery tickets or vouchers for a cup of coffee);
5. providing **benefits in kind** closely associated with the donation (for example egg-sharing arrangements);
6. introducing **financial incentives** that leave the donor in a significantly better financial position (p. 108).¹

Of these the first four are framed as being altruist-focused, with the final two being non-altruist-focused. This distinction drawn between these interventions is not a line between those which do or do not attract payments. For example, the Council places the offering of small tokens amongst the altruist-focused interventions. This is because such tokens would be of nominal monetary value and are not the kinds of things that would prompt a donation from an individual not already predisposed to do so (p. 140).¹ The purpose of such tokens is to express gratitude, but importantly they can also act as a way of conveying and reinforcing the message about the social good of donation.¹³ On the other hand, arrangements such as egg-sharing are placed on rung five of the ladder as a non-altruism-focused intervention. Unlike the case of small tokens, egg-sharing arrangements do offer the kind of encouragement that would induce a woman who would not otherwise have done so to donate eggs (p. 140).¹

Thus, the line in the sand with regards to altruism focuses on the motivations of the would-be donor and whether or not they would have been disposed to donate regardless of the intervention in question. Further, the distinction drawn between the altruism-focused and non-altruism-focused interventions does not necessarily represent the line between activities which ought to be viewed as ethical and those which ought not to be (p. 140).¹ The Council's approach and analysis here is to be welcomed for a number of reasons. First, the move away from viewing altruism and incentives to donate as antithetical opens the door in the policy debate to the shades of grey that exist and ought to be considered in relation to the regulation of the donation of human biomaterials. Secondly, while recognising that different interventions may have varying effects on an individual's willingness to donate, the report avoids making the erroneous claim that interventions, especially in the form of payments or other incentives, ought not to *induce* or *persuade* them to donate. As I have argued elsewhere, the very purpose of offering incentives is to prompt or persuade; "if individuals (or their families after death) were sufficiently motivated to make available their organs [or other biomaterials] . . . then this would negate the need to offer the incentive in the first place" (pp. 92-3).¹² Thirdly, it explicitly recognises that some non-monetary interventions can affect an individual's motivations and influence their actions to a greater extent than certain monetary payments or their equivalent. Finally, and related to the preceding two points, the report notes that the mere fact that an incentive is given is not indicative of a coercive influence which undermines consent, even if it changes the balance of costs and benefits to be weighed up. Instead, it recognises if such influence is present, it will be context-dependent and rely on the specifics of the incentive scheme proposed (p. 141).¹

In the round this contextualised approach and analysis of the relationship between payments and altruism a propos human biomaterials represents long-awaited progress with regards to recommendations for policy. Nevertheless, although the report argues that we should offer rewards or incentives to encourage donation, and even permit direct purchase, this is only the case in certain situations and for specific materials. A notable endorsement in the report is related to eggs for research: it advocates trialling a scheme of paying for eggs for research purposes. This is in contrast to the fact that similar recommendations are not made in relation to other tissues used for research purposes or for eggs used for reproductive purposes. Therefore, it is to these asymmetries that I now turn.

4. Eggs & other biomaterials: Justifying asymmetries?

The Council is clear that donors ought not to be left worse off financially because of their decision to donate and are supportive of the recent decision by the Human Fertilisation and Embryology Authority which raises the cap on the reimbursement of expenses for egg donation (for both treatment and

research).^{14,15} However, they advocate going beyond this with regards to eggs donated for research purposes. They propose that a pilot scheme of payments for egg donation for *research* be introduced. Such payments would go beyond mere recompense for loss of earnings and other directly incurred expenses. The reason given for this is that egg donation for research is broadly analogous to participation in first-in-human trials and payment would be "compensation for the time, inconvenience and discomfort involved in donating" (p. 184).¹ Yet, despite this, and being generally positive regarding egg-sharing arrangements, the report does not currently support payment beyond recompense for the donation of eggs for *treatment*, saying:

[There is] a clear distinction can be made between the position of donors who in return receive a benefit directly associated with their donation (in the case of egg sharers, the opportunity to receive treatment that would otherwise not be available to them), and those who are invited to donate on the basis of simple financial reward(p. 183).¹

In drawing a distinction between donation for research and donation for treatment an emphasis is placed on the notion of solidarity. The Council argues that "where there are no clear recipients (known or unknown) of the donated material, a move away from a primarily altruistic model of donation may not present a risk of undermining solidarity" (p. 183).¹ But how does the notion of solidarity help to tell us whether or not payments are ethically permissible?

4.1 Together we stand . . . sometimes

Solidarity in this report is seemingly being deployed as a normative justification for permitting or not permitting particular courses of action. If this is the case then it prompts us to ask *with whom* we are meant to be standing and in the pursuit of *which* common values. The answer is to be found where the report notes that "the potential gains by others [from research] are . . . uncertain, remote, and impossible to link with any identifiable individual" (p. 183).¹ This suggests that the requirements of solidarity are somehow fewer (or weaker) when it comes to those who are less identifiable, more remote from us (in time and perhaps distance), and where there is less certainty about the outcome of the research. I do not deny that the beneficiaries of any particular strand of research involving biomaterials may well be a more nebulous less identifiable group of people than those who directly benefit from transplants or egg donation for treatment. Nonetheless, we ought to question what we can justifiably mean when we use solidarity as a normative concept. When I speak of solidarity with my fellow man and woman, do I only stand with those who are near to me and (with) whom I can identify? And do I only stand with them when they are close both in terms of time and distance? If solidarity is to have any normative value, I doubt whether it should be interpreted in the kind of narrow context-specific sense it is seemingly deployed in this report. According Prainsack and Buyx, in another recent report "solidarity signifies

shared practices reflecting a collective commitment to carry 'costs' (financial, social, emotional, or otherwise) to assist others (p. 46)".¹⁶ Although not an official Council report this does cohere with the (sometimes) implicit use of the term in the *Human Bodies* report. Here solidarity is seen as "a communal commitment to the provision of materials needed by others for the preservation or improvement of their health" (p. 183).¹ On the face of it this would seem to encompass something more expansive than the treatment of 'other infertile women like me'; for example, 'others like me who benefit from health-related research'. Moral prohibitions and obligations, insofar as they extend to our fellow persons, would seem to rest on a much wider basis than mere synergies of particular personal attributes (e.g. infertility) held by those persons. Why it is morally incumbent upon me to aid those with infertility may have nothing to do with whether or not I am also infertile; instead this might be justified by an appeal to the well-being or flourishing of that particular person, or to the impact of infertility on their life plans, or even to the structure of the kind of society we want to live in.

Of course, the Council is using solidarity to a slightly different normative end; to argue that payments are ethically more problematic where they undermine solidarity. This is why payments-in-kind via egg-sharing is supported while direct payments for eggs for treatment are not; presumably those who are infertile are in some sense 'in it together' whereas the beneficiaries of research are not, or at least not to the same extent or in the same manner. After all, as Dawson and Verweij have recently noted a "core idea of solidarity is that the group as a whole shares the risks, burdens, or possible threats."¹⁷ However, whatever role recognising these shared exigencies might play, it is not clear that solidarity or an appeal to communal values can do the normative work needed here. There are plenty of values that persons in liberal society share, but the fact that they share them does not explain why payments ought or ought not to be permitted; for example, teachers may value education and so may their students, but this does not tell us anything about the permissibility of paying them to share their wisdom and knowledge with those who have less of those things. Likewise, an appeal to the "communal commitment to the provision of materials needed by others for the preservation or improvement of their health" (p. 183)¹ does not by itself tell us much about whether or not we can pay to get those things, let alone the reasons why.

This is not to say that there is no useful work to be done by a concept of solidarity, it just may not have a relevant normative function in this context. Instead a more profitable route might be to view the appeal to solidarity as an empirical psychological claim about what motivates people. If so, the appeal may merely have an explanatory function. It may tell us why women may be willing to donate some of their eggs to other women also in need of fertility treatment, but not for research. Indeed this is what the studies into egg-sharing looked at by the Council revealed (p. 163).¹ The consequence of this is that allowing egg-sharing in treatment will have a practical impact that permitting payments will not. Meanwhile in the

research context, absent the motivation of the reduced cost of IVF and payments may be required to achieve the desired outcome of increased numbers of eggs for research. Nevertheless, whether solidarity is going to function descriptively or normatively it is, as Dawson and Verweij note "important to articulate, outline, and discuss the meaning and status of solidarity as a concept" not in the least so we can get a clearer idea of where it sits "within our normative discourse" (p. 4).¹⁷

4.2 Payments & social meaning

As I noted earlier part of the reasoning presented in the report for considering payment for egg donation for research is the parallel with clinical trials involving healthy volunteers:

Like healthy volunteers in first-in-human trials, women who donate eggs for research undergo medical procedures that involve discomfort, inconvenience and potential health risk, with the aim of enhancing scientific knowledge and hence potentially producing long-term health benefit (p. 183).¹

Yet women who donate eggs for treatment undergo the exact same 'discomfort, inconvenience and potential health risk'. One response to this is to point out that justice is served for those who agree to egg-sharing. They get the requisite recompense and benefit through the reduction of the cost of their own fertility treatments. However, this still leaves the question of encouraging women to donate who are not themselves undergoing IVF treatment (assuming, of course, that this is, in the round, a good and desirable thing to encourage). In examining this we could return to solidarity. It is true that the women who agree to egg-sharing are to some extent involved in a common endeavour; they are undergoing fertility treatment in order to have children and so could be said to have a relevant connection to those other women who would benefit from receiving their eggs. But to only focus on these women would suggest that it is somehow more proper or ethical that women with fertility problems donate to other women with fertility problems. However, even though the report sees it as never acceptable to offer a direct payment in exchange for eggs for treatment, but supports a payment-in-kind (reduced cost fertility treatment), what makes this acceptable is the sense of connection between the act of donation and the benefit received. Yet, as the Council itself, accepts there are other values and reasons to be considered. This is why, solidarity aside, they place egg-sharing on the *non-altruist* focused part of their intervention ladder. This is recognition that there can be powerful motivations at play; motivations which one might argue could be greater even than enticing sums of cash. If this is correct, and I do not doubt that it is, then it is at least possible that there would be fewer pressures upon those women who are not themselves undergoing IVF but who might agree to donate in exchange for payment. In saying this we should note that the Council is not completely ruling out payments or financial incentives in this arena, what they are

concerned about is the social meaning of any payments or tokens which are given. Consequently, the report says:

The Council rejects outright the concept of paying a 'purchase' price for gametes, where any payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself (p. 180).¹

In this respect, for women who donate, but are not part of an egg-sharing arrangement, reward that is not framed as direct payment might be acceptable. This would be consistent with the approach to eggs for research where payment above expenses incurred is framed as compensation for 'discomfort, inconvenience and potential health risk'. However, it is explicitly acknowledged in the report that any such move would need to be preceded by robust empirical investigation into the effects on children of financial incentives for the donation of gametes (p. 182).¹

4.3 Other biomaterials for research

Whatever the arguments regarding parallels and distinctions between eggs for treatment and those for research, we might think that there are closer parallels to be drawn between the latter and other biomaterials for research. Let us consider again the reasoning presented in the report for considering payment for egg donation. As we saw earlier, the Council says:

[W]e consider that where there are no clear recipients (known or unknown) of the donated material, a move away from a primarily altruistic model of donation may not present a risk of undermining solidarity, as expressed for example in a communal commitment to the provision of materials needed by others for the preservation or improvement of their health (p. 13).¹

Further, it also argues:

[W]e suggest that another value, justice, becomes applicable here, and that, if donors are prepared to undertake these procedures to benefit scientific endeavour and the wider community, it is only just that their contribution should be explicitly recognised (pp. 13-4).¹

Here the report might just as well be describing the case for payments as applied to any tissue. These donations might also represent 'a communal commitment to the provision of materials needed by others for the preservation or improvement of their health' and be done to 'benefit scientific endeavour'. If this is the justification for payments then it would also seem to be a matter of justice that the contributions of donors of other biomaterials be 'explicitly recognised'. Yet despite the seemingly obvious applicability of these arguments to other biomaterials, an *ethical* assessment of payment for non-reproductive tissues for research is not dealt with by the report. One might argue that here there is an asymmetry between what is considered appropriate incentivisation when applied to eggs for research and that applied to the donation of other tissues for research. Although a

salient point distinguishing them might be that there is more time, inconvenience, and discomfort involved in egg donation, such a difference is merely one of degree and could be reflected in the level of recompense offered.

Despite this, I do not take it that there is a lack of support *in principle* for a payments scheme for non-reproductive tissues. The Council's position in this regard is a pragmatic one. There is not a lack of willingness on the part of individuals to donate non-reproductive tissue for research (p. 185)¹ and where there are perceived shortages this is often due to access problems instead (p. 92). For that reason, with regards to these tissues the focus in the report is on issues of consent, access to existing research materials, and infrastructure. Although similar reasons which justify permitting payments for eggs for research would also justify payments for other tissues, such incentives do need to be put in place if there are adequate biomaterials available to researchers. In a limited resource environment it would not be prudent to spend extra money on giving financial incentives where there is no obvious need to incentivise. Instead efforts are better focused at enabling researchers to access existing holdings of biomaterials.

5. Conclusion

As I said at the beginning this is a comprehensive and informative report and there is much to recommend it. The remit of the report is wide-ranging from therapeutic uses of organs and tissues, through the gamut of uses for research, to first-in-man trials. Although it is broad in its subject matter it manages to draw meaningful parallels between the different areas examined. I am not convinced by the distinction, underpinned by an apparently normative account of solidarity, which purports to show how we should approach the issue of financial incentives in therapy as opposed to research. Nonetheless, the general analysis given is nuanced and appropriately takes empirical and pragmatic points into account. The most significant contribution of this report is that it makes evident, in a publicly visible format, the shift in thinking with regards to human biomaterials which has taken place since its last report on the issue. It recognises that one size fits all proposals are not suitable, given the changing biomedical landscape, for encouraging and governing donation of biomaterials for medical and research purposes; as a document which makes recommendations for policy such an approach is to be welcomed.

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